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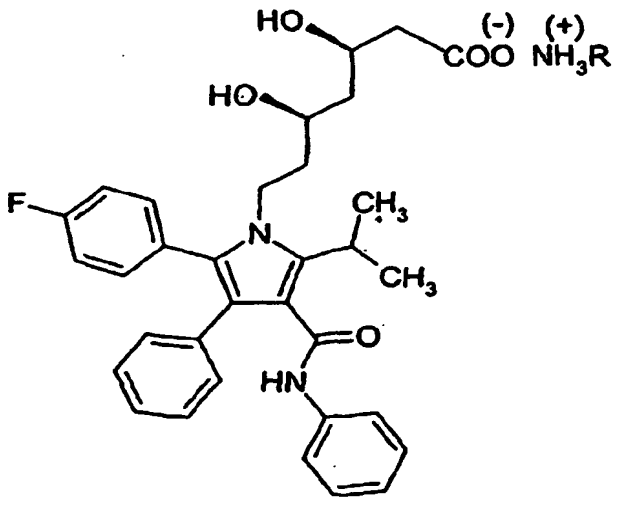
Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE,*

[Continued on next page]

(54) Title: PROCESS FOR THE SYNTHESIS OF AMORPHOUS ATORVASTATIN CALCIUM



(I)

(57) Abstract: The invention relates to a new process for the synthesis of amorphous atorvastatin calcium, which consists of dissolving the salt of the formula (I) of atorvastatin acid formed with a basic amino acid (I); in a mixture of water and a water miscible organic solvent, adding an aqueous solution of a water soluble calcium salt to the solution and isolating the so obtained entirely amorphous atorvastatin calcium of high purity by filtration.

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EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

Published:

— *with international search report*

— *with amended claims*

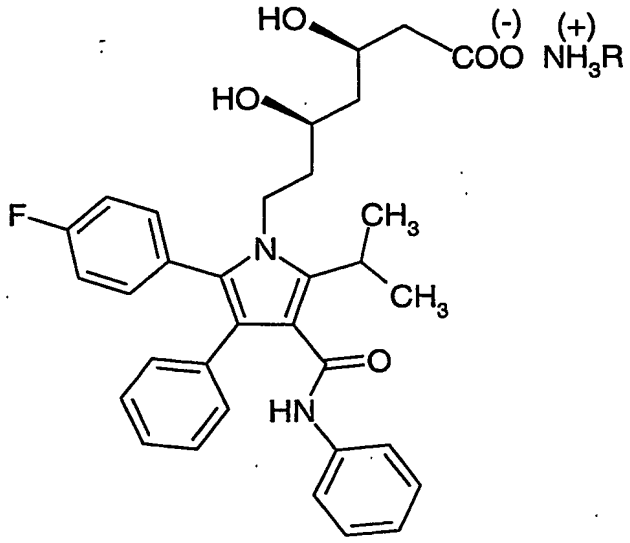
Date of publication of the amended claims: 18 November 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AMENDED CLAIMS

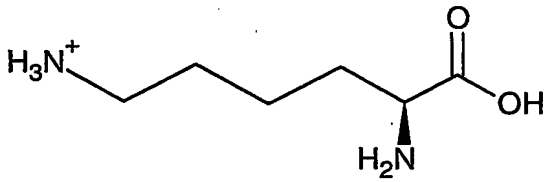
[received by the International Bureau on 22 September 2004 (22.09.04); original claims 1-3 replaced by amended claim 1 (1 page);]

A process for the synthesis of amorphous atorvastatin calcium characterized by dissolving the salt of the formula (I) of atorvastatin acid formed with a basic amino acid

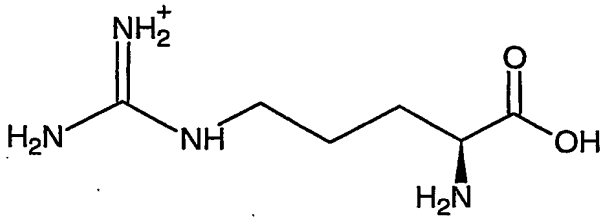


I

– wherein the meaning of R is the compound of formula (II) or (III)



(II)



(III)

– in a mixture of water and methanol, ethanol, isopropanol or acetone, adding an aqueous solution of a water soluble calcium salt to the solution and isolating the so obtained entirely amorphous atorvastatin calcium of high purity by filtration.

AMENDED SHEET (ARTICLE 19)